

## **REMARKS**

Claims 46-60 are currently pending in the application. Claims 46-51 are amended. The amendments find support in the specification and are discussed in the relevant sections below. No new matter is added.

### **Claim Amendments**

Claims 46-51 have been amended herein to include, as a ligand of the GPR86 receptor, two other agonists of this receptor, namely, 2MeSADP and ADPbetaS. Support for this amendment may be found throughout the specification, and at least at page 4, lines 13-21, and in Figure 4A. Applicants request entry and consideration of the amendments.

### **Allowed Claims**

The Office Action indicates that claims 46, 47, 50, and 51 are in condition for allowance. Applicants acknowledge this, and thank the Examiner for his close attention to the patentability of these claims.

### **Rejection of Claims 48, 49, and 52-60 Under 35 U.S.C. §112, Second Paragraph**

The Office Action states that claims 48, 49, and 52-60 stand rejected under 35 U.S.C. §112, second paragraph as being indefinite. The Office Action states that where claims 48 and 49 recite in the method step (c) “at least 10% of the amount induced by said ADP”, that it is not clear how the effect of a candidate modulator or agent is compared with that of ADP because the claim does not expressly recite concentrations of each which are to be used in the method. The Office Action concludes that it is “not clear what the metes and bounds of the term are, rendering the claims indefinite”. There is no rationale or basis provided in the rejection to support the Office Action’s contention that claims 48, 49, and 52-60 are indefinite.

The function of 35 U.S.C. §112, second paragraph, and thus the focus of an analysis of whether a claim complies with the statute, is to ensure that the claims apprise one of skill in the art of their scope and, therefore, serve the notice function required by the statute; by providing clear warning to others as to what constitutes infringement. See, e.g., *Solomon v. Kimberly-*

*Clark Corp.*, 216 F.3d 1372, 1379 (Fed. Cir. 2000); MPEP, §2173.02. The case law is clear that a decision on whether a claim is invalid under § 112, second paragraph, requires a determination of whether those skilled in the art would understand what is claimed when the claim is read in light of the specification. *Seattle Box Co. v. Industrial Crating & Packing Inc.*, 731 F.2d 818, 826, 221 U.S.P.Q. (BNA) 568, 574 (Fed. Cir. 1984); *In re Marosi*, 710 F.2d 799, 803, 218 U.S.P.Q. (BNA) 289, 292 (Fed. Cir. 1983). Applicants are only required to claim the invention with a reasonable degree of particularity and distinctness; satisfaction of §112, second paragraph is to be judged using a reasonableness standard. MPEP, §2173.02.

Applicants submit that claims 48 and 49 fully comply with the requirements under §112, second paragraph. One of ordinary skill in the art would understand from a reading of claim 48 and 49 whether the method that they were performing fell within the scope of the claimed invention. That is, one of skill in the art would understand that Applicants are claiming a method of identifying an agonist or agent that increases the signaling of GPR86 by comparing the activity measured in response to the candidate versus one of ADP, 2MeSADP and ADPbetaS, and determining whether the activity of the candidate is at least 10% that of one of ADP, 2MeSADP and ADPbetaS. The method as claimed is clear and definite and, one of skill in the art would thus, be able to determine readily whether or not they were performing the claimed method.

The Office Action asserts that because the claim does not recite the concentrations of the compounds used in the method, that one of skill in the art would not understand what was claimed, and would not understand how to compare the signaling of the candidate modulator and ADP, 2MeSADP and ADPbetaS. The claim, read in view of the specification, makes it clear how to compare the signaling, and the absence of a recitation of the concentrations of the compounds used does not impair this clarity. The specification provides ample teachings of how one of skill in the art would perform the claimed screening methods (see, e.g., pages 32-45, 48-50), and provides examples of concentrations of ADP and candidate modulators which may be used in the invention (see, e.g., pages 12-13, 26, 28, and 32). Thus, one of ordinary skill in the art, by reading the claims in view of the specification, would understand the metes and bounds of the invention.

While Applicants acknowledge that if one of skill in the art were to use a low concentration of one of ADP, 2MeSADP and ADPbetaS, and a very high concentration of a candidate modulator, then the modulator may be deemed to be an agonist because the high concentration produced a signaling activity which was at least 10% of that measured in response to one of ADP, 2MeSADP and ADPbetaS. The fact that the claimed methods may be performed in a manner that produces false positive results is irrelevant and does not render the claim vague or indefinite. Applicants emphasize that the clarity of the claim is judged from the perspective of one of ordinary skill in the art; one of ordinary skill in the art would have a basic understanding of how to compare the activity of compounds and would understand that it is not scientifically advisable to use strikingly divergent concentrations. One of ordinary skill in the art, in light of the specification, would not require the claim to recite concentrations of compounds to be compared in order to determine whether or not they were performing the claimed method. **The function of the claim is not to act as a laboratory manual.** If the logic asserted in the Office Action were to prevail, then it would follow that the claim should also recite the temperatures at which each step is carried out (because one of skill in the art could use a temperature in screening a candidate compound which is more favorable for GPR86 activity, thus yielding a false result), the compositions of all the solutions used for each step of the method (because one of skill in the art could use different solutions and buffers for screening a candidate than for ADP, yielding inaccurate results), the commercial supplier of the candidate modulator and of ADP (because different suppliers may have different standards for their reagents, and therefore the candidate modulator and ADP used by one of skill in the art may not be of the same quality, thus giving inaccurate results), and so on. Clearly, this is not the legal standard under 35 U.S.C. §112. Applicants submit the claims are definite as written and clearly set forth the metes and bounds of the claimed invention, and accordingly request that the rejection be reconsidered and withdrawn.

Applicant submits that all claims are allowable as written and respectfully request early favorable action by the Examiner. If the Examiner believes that a telephone conversation with Applicant's attorney/agent would expedite prosecution of this application, the Examiner is cordially invited to call the undersigned attorney/agent of record.

Date:

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